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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,367	03/10/2004	Janel E. Young	ETH5095CIP	4470

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
11/14/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/797,367	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING FUBARA	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *28,30-32,34,39 and 41* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *28,30-32, 34, 39 and 41* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Applicant's arguments, see remarks, filed 10/11/2011, with respect to the rejection(s) of claim(s) 28, 30-32 and 39 under 35 USC 102; claims 28 and 30 under 35 USC 103; claims 28 and 41 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the prior art cited below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 41 depends on claim 28. Claims 28 recites composition that consists of biodegradable polymer and tranilast and optional additional agent. Tranilast is collagen synthesis inhibitor. It is thus unclear how the additional agent is an agent that inhibits collagen synthesis which also includes tranilast.

6. Correction and/or explanation is requested.

7. Tranilast is also anti-proliferative, anti-inflammatory and anti-fibrotic. Applicant may recite the specific disclosed drugs that meet the limitation of the broad category of drugs recited in claim 41.

8. Claim 41 has not been rejected over art because it is unclear what applicant intends the additional therapeutic agents in claim 41 to be. Once claim 41 is clarified, then the claim can be properly searched for art.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 28 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamane et al. ("Spinning of Poly (caprolactone)/Drug Blends and Drug Release Behavior from Blend Fibers" in Fiber, 1999, pp 261-266, English Abstract).

11. Claim 28 is a composition that consists of biodegradable polymer and tranilast. The polymer is in the form of a film, foam, fiber or filament. The tranilast is present in effective amount to inhibit post-operative adhesions upon local administration. Claim 28 has not recited the amount considered effective by the examined invention. Inhibition of post-operative adhesion is characteristic effect of the tranilast. A composition that consists of biodegradable polymer and tranilast that anticipates the claimed composition would also be capable of local and non-systemic administration as the claimed composition.

12. Yamane: Yamane discloses a composition consisting of caprolactone biodegradable polyester drug releasing fiber and tranilast (see the English abstract). The drug-releasing fiber containing the tranilast anticipates claim 28. Effective amount is any amount deemed effective by the practitioner; the biodegradable polycaprolactone polyester polymer anticipates the biodegradable polymer of claim 30. The composition providing a single dose administration of tranilast and the composition providing for sustained release is the characteristic of the composition of claim 28 and the composition of Yamane inherently has these characteristics so that claims 31 and 32 are met.

13. Claims 28 and 30-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsuji et al. ("Biodegradable stents as a platform to drug loading" in International Journal of Cardiovascular Interventions 2003, No. 5, 13–16, March 1, 2003).

14. Tsuji discloses monofilament of polylactic acid biodegradable polyester that contains tranilast (see the whole document). The monofilament is a biodegradable stent consisting of the biodegradable polyester PLLA and is locally administered. Thus the PLLA biodegradable stent consisting of the tranilast and the monofilament of PLLA anticipates claim 28 in that effective amount is any amount deemed effective by the practitioner, the biodegradable PLLA polyester polymer anticipates the biodegradable polymer of claim 30. The composition providing a single dose administration of tranilast and the composition providing for sustained release is the characteristic of the composition of claim 28 and the composition of Yamane inherently has these characteristics so that claims 31 and 32 are met.

15. Claims 28, 30-32 and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by HELMUS (WO 03/068288).

16. HELMUS discloses biodegradable stents for delivery of therapeutic agents, non-genetic and genetic (abstract; paragraphs [0058]-[0066]). Specifically the therapeutic agents are not limited in HELMUS. For example one of the therapeutic agents named is tranilast. The biodegradable stent or medical device can be fully biodegradable or contain non biodegradable core (see the abstract; paragraphs [0009]-[0030]); paragraph [0031] describes a medical device in which the core and the coating material are both biodegradable or bioerodible. The core or the coating material or both core and coating material in HELMUS contain therein or thereon at least one therapeutic agent (paragraph [0016]). In one embodiment, the entire medical device is biodegradable and comprises both biodegradable core and biodegradable coating (paragraph [0046]). When the entire medical device is biodegradable, the polymer of the core is collagen, or hyaluronic acid or cellulosic polymers such as hydroxypropylmethylcellulose, e.g., Klucel®; polyethyleneoxide, e.g. Polyox®; polyvinylpyrrolidone; dextran and copolymers of polyethyleneoxide with polypropyleneoxide, e.g., Pluronic® (paragraph [0048]); the polymer in the core containing thereon or therein the at least one therapeutic agent is woven or braided network of monofilament or multifilament or woven or braided filaments or fibers and the braided network may be coated with biodegradable polymer (paragraph [0049]); that is polyester or polysaccharide such as hyaluronic acid, chitosan, gelatin or collagen, polyamino acid or polypeptides (paragraph [0039]).

17. Thus when the fully biodegradable medical device consisting thereon tranilast on biodegradable core made from the biodegradable polymer such as collagen, or hyaluronic acid or

cellulosic polymers such as hydroxypropylmethylcellulose, e.g., Klucel®; polyethyleneoxide, e.g. Polyox®; polyvinylpyrrolidone; dextran and copolymers of polyethyleneoxide with polypropyleneoxide, e.g., Pluronic® and coating of polyester or polysaccharide such as hyaluronic acid, chitosan, gelatin or collagen, polyamino acid or polypeptides, claims 28, 30 and 39 are met. The composition providing a single dose administration of tranilast and the composition providing for sustained release is the characteristic of the composition of claim 28 and the composition of HELMUS inherently has these characteristics so that claims 31 and 32 are met.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 28 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al. ("Spinning of Poly (caprolactone)/Drug Blends and Drug Release Behavior from

Blend Fibers" in Fiber, 1999, pp 261-266, English Abstract) or Tsuji et al. ("Biodegradable stents as a platform to drug loading" in International Journal of Cardiovascular Interventions 2003, No. 5, 13–16, March 1, 2003), each in view of Hunter et al. (US 20020052404).

21. Yamane in view of Hunter: Yamane has been described above to anticipate claim 28. Yamane uses polycaprolactone polyester as the carrier for tranilast. Yamane does not teach the polymer of claim 39. However, Hunter teaches that carriers such as carbohydrates and polysaccharides such as starch, cellulose, dextran, methylcellulose, and hyaluronic acid, proteins or polypeptides such as albumin, collagen and gelatin, lactic acid and glycolic acid, poly (caprolactone), poly (lactic acid), copolymers of poly (lactic acid) and poly (caprolactone), gelatin, hyaluronic acid, collagen matrices, and albumin are carriers for hydrophobic drugs such as tranilast (see the whole document with emphasis on paragraphs [0020], [0021], [0158], [0165], [0176], [0200]).

22. One carrier can be used in place of the other. Therefore, it would have been obvious to substitute one polymer carrier for another and expect to have the desired release of the tranilast from the polymer.

23. Tsuji in view of Hunter: Tsuji has been described above to anticipate claim 28. Tsuji8 uses PLLA polyester as the carrier for tranilast. Tsuji does not teach the polymer of claim 39. However, Hunter teaches that carriers such as carbohydrates and polysaccharides such as starch, cellulose, dextran, methylcellulose, and hyaluronic acid, proteins or polypeptides such as albumin, collagen and gelatin, lactic acid and glycolic acid, poly (caprolactone), poly (lactic acid), copolymers of poly (lactic acid) and poly (caprolactone), gelatin, hyaluronic acid, collagen

matrices, and albumin are carriers for hydrophobic drugs such as tranilast (see the whole document with emphasis on paragraphs [0020], [0021], [0158], [0165], [0176], [0200]).

24. One carrier can be used in place of the other. Therefore, it would have been obvious to substitute one polymer carrier for another and expect to have the desired release of the tranilast from the polymer.

25. Claims 28 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al. ("Spinning of Poly (caprolactone)/Drug Blends and Drug Release Behavior from Blend Fibers" in Fiber, 1999, pp 261-266, English Abstract) or Tsuji et al. ("Biodegradable stents as a platform to drug loading" in International Journal of Cardiovascular Interventions 2003, No. 5, 13–16, March 1, 2003) or HELMUS (WO 03/068288), each in view of Fukuyama et al. (US 6,019,104) or Bunnett et al. (US 5,958,407).

26. Yamane in view of Fukuyama or Bunnett: Yamane has been described above to anticipate claim 28. Yamane does not disclose the amount of tranilast recited as mg/kg in claim 34. But Tranilast has been known to be administered in doses of 60 mg/kg (see column 2, lines 60, 61) and 30-100 mg.kg 0r 3-10 mg/kg (see column 6, line 67 to column 7, line 1 of Bunnett). Taking the teachings of Yamane and Fukuyama or Bunnett, one having ordinary skill in the art at the time the invention was made, guided by the disclosure of Fukuyama or Bunnett regarding amount tranilast , the artisan would have been motivated to optimize the composition of Yamane such that effective amount of tranilast is delivered successfully.

27. Tsuji in view of Fukuyama or Bunnett: Tsuji has been described above to anticipate claim 28. Tsuji does not disclose the amount of tranilast recited as mg/kg in claim 34. But Tranilast

has been known to be administered in doses of 60 mg/kg (see column 2, lines 60, 61) and 30-100 mg.kg 0r 3-10 mg/kg (see column 6, line 67 to column 7, line 1 of Bunnett). Taking the teachings of Tsuji and Fukuyama or Bunnett, one having ordinary skill in the art at the time the invention was made, guided by the disclosure of Fukuyama or Bunnett regarding amount tranilast , the artisan would have been motivated to optimize the composition of Tsuji such that effective amount of tranilast is delivered successfully.

28. HELMUS in view of Fukuyama or Bunnett: HELMUS has been described above to anticipate claim 28. HELMUS does not disclose the amount of tranilast recited as mg/kg in claim 34. But Tranilast has been known to be administered in doses of 60 mg/kg (see column 2, lines 60, 61) and 30-100 mg.kg 0r 3-10 mg/kg (see column 6, line 67 to column 7, line 1 of Bunnett). Taking the teachings of HELMUS and Fukuyama or Bunnett, one having ordinary skill in the art at the time the invention was made, guided by the disclosure of Fukuyama or Bunnett regarding amount tranilast , the artisan would have been motivated to optimize the composition of HELMUS such that effective amount of tranilast is delivered successfully.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

30. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

31. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. Claims 28, 30-32, 34, 39 and 41 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 19, 21-23, 27, 28, 31, 34, 37, 39-41 of copending Application No. 10/780,452 (US 20050181023) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

33. The compositions of copending claims 14, 19, 21-23, 27, 28, 31, 34, 37, 39-41 of application number 10/780,452 contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening.

34. This is a provisional obviousness-type double patenting rejection.

35. Claims 28, 30-32, 39 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of copending Application No. 12/021,546 (US 20080119494) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

36. The method of copending claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of 12/021,546 uses compositions that contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however

known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening or post-operative adhesions.

37. This is a provisional obviousness-type double patenting rejection.

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Takehana et al. (US 6,303,655 B1) or Isaji et al. (US 6,376,543 B1).

39. Isaji and Takehana: Isaji and Takehana, each, disclose sustained release preparation consisting of tranilast and biodegradable polymer such as lactic acid polymer and lactic acid-glycolic acid (Isaji at column 3, line 62 to column 4, line 8; Takehana at column 3, lines 34-46). Isaji and Takehana are both silent as to the form of the polymer of composition, that is, film or foam or fiber or filament.

40. No claim is allowed.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

43. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613